

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8424

Bartle, C.J.

March 11, 2010

Marilyn Ware ("Ms. Ware" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bradley M. Leonard, M.D., F.A.C.C. Based on an echocardiogram dated January 12, 2002, Dr. Leonard attested in Part II of Ms. Ware's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.³

2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Leonard also attested that Ms. Ware suffered from mild aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$449,381.⁴

In the report of claimant's echocardiogram, Dr. Leonard stated that claimant had "moderate mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2002, the Trust notified Ms. Ware that her claim had been selected for audit.⁵ Despite an opportunity to do so, claimant did not submit additional medical information in support of her claim for review by the auditing cardiologist. In

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Under the Settlement Agreement, Wyeth or the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures Order ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit the level of claimant's mitral regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

October, 2002, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Zwas concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because only "physiologic mitral regurgitation [was] seen on this poor quality study."⁶

Based on the auditing cardiologist's finding of physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Ware's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.⁷ The Trust then applied to the court for issuance of an Order to show cause why Ms. Ware's claim should be paid. On February 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2757 (Feb. 19, 2003).

6. As stated in the Auditing Cardiologist Worksheet, physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or ≤ 5% RJA/LAA."

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Ware's claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 18, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Ware submitted a supplemental opinion from Dr. Leonard, who confirmed his previous finding that claimant had moderate mitral regurgitation, which he estimated to be "at least 30-35% if not greater"⁹ Claimant also argues that Dr. Leonard is a highly-qualified cardiologist who correctly measured Ms. Ware's level of mitral regurgitation. Claimant contends that the court should disregard the findings of the auditing cardiologist because the auditing cardiologist only disputes Dr. Leonard's finding by estimating Ms. Ware's level of regurgitation, "but does not actually calculate the RJA/LAA" ratio. Ms. Ware further avers that the auditing cardiologist simply substituted Dr. Leonard's determination with her "opinion" and failed to determine whether there was a reasonable medical

9. Claimant also notes that she requested, but did not receive, an extension from the Trust in order to obtain a Fund A Screening Program echocardiogram. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement). Claimant, however, does not explain how she is prejudiced by her inability to obtain a Screening Program echocardiogram. In addition, as we previously have held, "[t]he Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits." PTO No. 8380 at 10-11 (Jan. 7, 2010) (citation omitted).

basis for Dr. Leonard's finding of moderate mitral regurgitation.¹⁰ Finally, claimant asserts that due process requires a hearing with both the attesting physician and auditing cardiologist.¹¹

In response, the Trust argues that the auditing cardiologist assessed claimant's echocardiogram in accordance with the Settlement Agreement and that the audit of Ms. Ware's claim was conducted in accordance with the Settlement Agreement and the Audit Policies and Procedures. The Trust also states that due process does not, contrary to claimant's argument, require a hearing with both the attesting physician and the auditing cardiologist. In addition, the Trust asserts that the auditing cardiologist found that claimant had physiologic regurgitation. Finally, the Trust notes that claimant's attesting physician also estimated her level of mitral regurgitation and failed to provide precise measurements.

10. Claimant also argues that she was prejudiced because the auditing cardiologist noted technical difficulties with her echocardiogram tape but did not provide her with an opportunity to submit a new tape. We disagree. Although the auditing cardiologist noted that the tape was of "poor quality," she was able to evaluate claimant's echocardiogram. Accordingly, the Trust was not required to provide claimant with an opportunity to submit a new echocardiogram tape.

11. In addition, claimant argues that she should receive Matrix Benefits because the Trust did not timely file its application for an Order to show cause. Claimant, however, failed to demonstrate how she was prejudiced by this delay. As we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." PTO No. 6339 at 13 n.10 (May 25, 2006).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Specifically, Dr. Vigilante found that:

[O]nly mild mitral regurgitation was noted in the apical four chamber view. This mitral regurgitant jet in the apical four chamber view was only slightly above the closure point of the mitral leaflets. RJA/LAA was less than 10%. At no time during this study did the mitral regurgitant jet come close to approaching 20% of the left atrial area.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the diagnoses of physiologic and mild mitral regurgitation offered by Dr. Zwas and Dr. Vigilante, respectively.¹² Claimant does not refute or respond to Dr. Vigilante's specific conclusion that "[i]t would be impossible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this study." On this basis alone, claimant has failed to meet her burden in proving that there is a reasonable medical basis for her claim.

Claimant instead merely questions the methodology Dr. Zwas used in assessing Ms. Ware's level of mitral

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

regurgitation. We disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15 (Nov. 14, 2002). Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640. On this basis as well, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.¹³

We also disagree with claimant that Dr. Zwas merely substituted her finding with that of the attesting physician and failed to evaluate whether there was a reasonable medical basis for his finding of moderate mitral regurgitation. To the contrary, Dr. Zwas reviewed claimant's echocardiogram and found that it demonstrated only physiologic regurgitation, which is significantly below the threshold for moderate mitral

13. Significantly, claimant ignores that her attesting physician also estimated her level of mitral regurgitation.

regurgitation and the attesting physician's estimate of "30-35%." Accordingly, Dr. Zwas found no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. The auditing cardiologist's conclusion was confirmed by Dr. Vigilante, who found claimant's mitral regurgitation to be less than 10%. Thus, contrary to claimant's argument, the auditing cardiologist did not merely substitute her opinion for the diagnosis of the attesting physician.

Finally, we reject claimant's position that "due process" requires a hearing with both the attesting physician and auditing cardiologist. The Audit Policies and Procedures, as approved by this court, comply with due process requirements, because claimant has had notice and an opportunity to present her evidence in support of her claim. Further, the Audit Policies and Procedures specifically provide that "[a]n Application will be decided without a Hearing unless the Court orders otherwise." Audit Policies and Procedures § VI.P. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See id. § VI.D. As the existing Show Cause Record establishes that claimant has not met her burden, a hearing is unnecessary.¹⁴

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable

14. This is particularly true given that, as noted above, claimant did not file any response to the Technical Advisor Report.

medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Ware's claim for Matrix Benefits.